



PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Attorney Docket No.: 107223.167 (US2))

Applicant(s): Sanghvi, et al.

Serial No.: 10/630,239

Examiner: Not Yet Assigned

Filed: July 30, 2003

Group Art Unit: Not Yet Assigned

For: SUSTAINED RELEASE FORMULATIONS OF METFORMIN

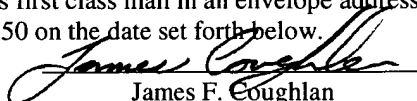
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE UNDER 37 C.F.R. 1.8(a)

I hereby certify that this correspondence is being as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria VA. 22313-1450 on the date set forth below.

12-17-03

Date


James F. Coughlan

TRANSMITTAL LETTER

Commissioner:

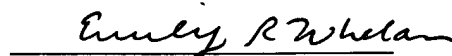
Enclosed for filing in the above-identified application are the following documents:

- 1.) Information Disclosure Statement, including 40 references;
- 2.) Form PTO-1449; and
- 3.) Return Postcard.

Please charge any deficiency or credit any overpayment in connection with this matter to Deposit account No. 08-0219.

Respectfully submitted,

Dated: 12/17/03


Emily R. Whelan
Registration No. 50,391

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PATENT

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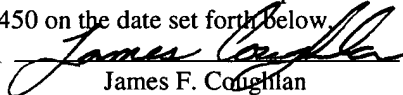
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12-17-03

Date


James F. Coughlan

INFORMATION DISCLOSURE STATEMENT

Commissioner:

Applicant and his attorney are aware of the following publications and information listed on the attached PTO Form 1449, and in accordance with 37 CFR §1.97 hereby submits these publications for the Examiner's consideration.

Pursuant to 37 C.F.R. §1.97, Applicant hereby makes of record the documents listed on the attached Form PTO-1449.

It is respectfully requested that the information above be expressly considered during the prosecution of this application and that the publications be made of record therein and appear among the "References Cited" on any patent to issue therefrom. In this regard, it is requested that the Examiner initial and return a copy of the enclosed Form PTO-1449 with the next Patent Office Communication.

This submission does not represent that a search has been made and does not constitute an admission that the listed documents are material to patentability or that the listed documents are prior art. If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

U.S.S.N. 10/630,239
Sanghvi, et al.

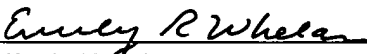
Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits and is therefore submitted as both timely and proper; therefore, no fees are believed to be due.

The Commissioner, however, is hereby authorized to charge any fee deficiency or credit any overpayment to Deposit Account No. 08-0219.

Respectfully submitted,

Date: 12/17/03


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INFORMATION DISCLOSURE IN AN APPLICATION

(Use several sheets if necessary)

Sheet 1 OF 2

 Docket Number
107223.167 US2

 Application Number
10/630,239

 Applicant
Sanghvi, et al.

 Filing Date
July 30, 2003

 Group Art Unit
Not yet assigned

U.S. Patent Documents

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | NAME | CLASS | SUBCLASS | FILING DATE IF APPROPRIATE |
|---------------------|--------------------|----------|------------------|-------|----------|-------------------------------|
| | 5,128,143 | 7/7/92 | Baichwal, et al. | 424 | 464 | |
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| | 5,455,046 | 8/29/95 | Kataumi, et al. | 74 | 527 | |
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| | 5,330,767 | 7/19/94 | Yamamoto, et al. | 424 | 497 | |
| | 5,611,971 | 3/18/97 | Maedera, et al. | 264 | 4.1 | |
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| | 3,629,393 | 12/21/97 | Nakamoto, et al. | 424 | 22 | |

Foreign Patent Documents

| EXAMINER INITIAL | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
|---------------------|--------------------|----------|---------|-------|----------|-------------|----|
| | | | | | | YES | NO |
| | 99/47128 | 9/23/99 | WO | | | | |
| | 97/17975 | 5/22/97 | WO | | | | |
| | 44 32 757 | 3/21/96 | DE | | | YES | |
| | 0 749 751 | 12/27/96 | EP | | | | |
| | 0 580 428 | 10/1/97 | EP | | | | |
| | 0 709 085 | 5/1/96 | EP | | | | |
| | 0 531 497 | 8/13/97 | EP | | | | |
| | 0 251 459 | 7/8/92 | EP | | | | |

Other Documents (Including Author, Title, Date Pertinent Pages, Etc.)

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| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if citation is considered, whether or not citation is in conformance with MPEP § 609: Draw Line through citation if not conformance and not considered. Include copy with next communication to applicant. | |

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|--|---|----|---|---------------------------------|------------------------------------|
| Subt. Form PTO-1449 | | | | Docket Number 107223.167 US2 | Application Number 10/630,239 |
| <p style="text-align: center;">INFORMATION DISCLOSURE IN AN APPLICATION</p> <p style="text-align: center;">Use several sheets if necessary)</p> | | | | Applicant Sanghvi, et al. | |
| | | | | Filing Date July 30, 2003 | Group Art Unit Not yet assigned |
| Sheet | 2 | OF | 2 | | |
| | | | | | |



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| A1 | Campbell, et al., "A Clinical Evaluation of a Delayed Release Preparation of Metformin," <i>J Int Med Res</i> , Vol. 1, pp.551-556 (1973) |
| A2 | Pentikainen, "Bioavailability of Metformin. Comparison of solution, rapidly dissolving tablet, and three sustained release products," <i>Int J Clin Pharmacol, Ther and Toxicol</i> , Vol. 4, pp. 213-220 (1986) |
| A3 | Abdallah, et al., "Preparation and evaluation of metformin hydrochloride controlled-release tablets," <i>S.T.P. Pharma</i> , Vol. 4(1), pp. 15-20 (1988) |
| A4 | Karttunen, et al., "The Pharmacokinetics of metformin: a comparison of the properties of a rapid-release and sustained-release preparation," <i>Int J Clin Pharmacol, Ther and Toxicol</i> , Vol. 21(1), pp. 31-36 (1983) |
| A5 | Mosby's GenRx, "Drug Names – Metformin Hydrochloride (3204) Categories, Brand Names, Formularies & Cost of Therapy," (1998) pp.1-17 |
| A6 | Saleh, "Tablets produced under licence Do they have the same dissolution characteristics and drug content uniformity as the original ones? Example: metformin hydrochloride sustained-release tablets," <i>S.T.P. Pharma</i> , Vol. 6(8), pp. 598-603 (1990) |
| A7 | Grdinic, et al., "Comparison of in-vitro release and renal elimination of 1-butylbiguanide from times-release oral antidiabetic preparations," <i>Acta Pharm. Jugoslav.</i> , Vol. 29, pp. 215-221 (1979) |
| A8 | Dimitrijevic, et al., "Electro-Responsive Release From A Chondroitin Sulphate Hydrogel," <i>J. Pharm. Pharmacol.</i> , Vol. 47, pp. 1058 (1995) |
| A9 | Karttunen, "The Influence of Pharmaceutical Formulation on the Gastrointestinal Side Effects of Metformin," <i>Scandinavian Society for the Study of Diabetes</i> , 15 th Annual Meeting, Norway (1980) |
| A10 | Noel, "Kinetic Study of Normal and Sustained Release Dosage Forms of Metformin in Normal Subjects," <i>Research and Clinical Forums</i> , Vol. 1(4), pp. 35-50 (1979) |
| A11 | Noel, "Kinetic Study of Normal and Sustained Release Dosage Forms of Metformin in Normal Subjects," <i>Journal of International Biomedical Information and Data</i> , Vol. 1(1), pp. 9-20 (1980) |
| A12 | Bristol-Myers Squibb, "Glucophage XR (Metformin HCl extended-release) Tablets, Rx," <i>FDA Website</i> , (Posted October 20, 2000) |
| A13 | "Glucophage Retard," <i>The Rote Liste</i> (1993) |
| A14 | Araman, et al., "In Vivo-In Vitro Correlation of Prolinged Release Metformin HCL Tablets Prepared with Coating Materials," <i>Supplement F, Supplement to Pharmaceutisch Weekblad Scientific Edition</i> , 1 st European Congress of Pharmaceutical Science, Vol. 14(5) (1992) |
| A15 | Stanforth, "Synergistically Interacting Heterodisperse Polysaccharides – Function in Achieving Controllable Drug Delivery," <i>American Chemical Society</i> (1993) |

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